

USSN 09/975,132

REMARKS

The present application was originally filed with 52 Claims. In a Restriction Requirement mailed October 2, 2003, the Examiner restricted the Claims into six Groups:

- 1) Group I contains Claims 1-22, directed to processes for enhancing secretion of a polypeptide;
- 2) Group II contains Claim 23, directed to methods for reducing the susceptibility of a polypeptide to an extracellular protease;
- 3) Group III contains Claims 24-26, directed to an expression cassette;
- 4) Group IV contains Claims 30-38, directed to a recombinant protein;
- 5) Group V contains Claims 29-44, directed to a chimeric polypeptide; and
- 6) Group VI contains Claims 45-52, directed to a nucleic acid construct.

In a Response filed November 3, 2003, Applicant traversed the Restriction Requirement and elected the Claims in Group I (Claims 1-22), directed to processes for enhanced secretion of a polypeptide. Applicant cancelled Claims 23-52, but reserved the right to file Divisional application(s) to pursue these cancelled Claims.

In the present Office Action, the Examiner has indicated that Claims 6, 7, 17, 18, 21 and 22, which recite lysine (K) and/or asparagine (N) are not entitled to the priority date of Provisional Application 60/239531, as these specific amino acids are not explicitly recited in the Provisional filing.

The Examiner's rejections in the present Office Action are addressed in the following order:

- 1) Claims 1-22 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite; and
- 2) Claims 1, 2, 3 and 8-14 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not meeting the written description requirement.

1) The Claims are Definite

The Examiner has rejected Claims 1-22 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Examiner indicates that the preamble renders the Claims indefinite by reciting a method for enhanced secretion of a polypeptide "in" bacteria. In order to more clearly

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recite the Claim elements and eliminate confusion, Applicant has amended the Claim to recite the enhanced secretion of polypeptides *by* bacteria, rather than "in." Applicant respectfully submits that the amended Claims are definite.

In addition, the Examiner indicates that the use of "N" (asparagine) in Claims 6, 18, and 22 represents a positively charged amino acid, while the art accepts that asparagine is a polar, uncharged amino acid. Applicant respectfully submits that the Examiner is correct and indeed, the present Specification indicates this fact (See, page 10, lines 10-22). Applicant respectfully submits that the inclusion of "N" in these Claims was an inadvertent error and have amended Claim 6 to recite that the amino acid is lysine (K) and "N" has been deleted. In addition, Claims 18 and 21 have been cancelled without prejudice. Applicant respectfully submits that the Claims are definite and requests that this rejection be withdrawn.

2) The Written Description Requirement is Met

The Examiner has rejected Claims 1, 2, 3, and 8-14 under 35 U.S.C. §112, first paragraph as allegedly not meeting the written description requirement. In particular, the Examiner argues that the Claims "... embrace a broad genus of DNA sequences encoding a number of different addition [sic] of [sic] substitutions of amino acids to the carboxy terminus of an amino acid tag of a polypeptide The specification does not disclose how each of these modifications increase yield of a protein nor how many or what modifications required [sic]." (Office Action, page 5).

While Applicant must respectfully disagree with the Examiner's arguments, in order to further Applicant's business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, Applicant has amended Claims 1, 3 and 14 to recite that the tag comprises one or two amino acid residues (Claim 1 includes the further limitation that the amino acid residues are negatively charged), while Claims 2, 7, and 18 have been cancelled without prejudice. No new matter is added by these amendments. Applicant reserve the right to pursue the originally filed and/or broader Claims in subsequent application(s). In addition, Claim 6 has been amended to delete the improper recitation of "N." Applicant respectfully submits that the amended Claims are allowable and requests that the case be allowed.

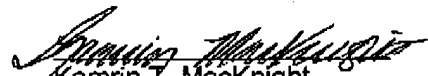
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CONCLUSION

All grounds of rejection and objection of the Office Action of February 17, 2004, having been addressed, reconsideration of the application is respectfully requested. Applicant respectfully submits that the pending Claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-5838.

Respectfully submitted,

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